

The Island Capsule

Newsletter of the Prince Edward Island Pharmacy Board

December 2007

PRINCE EDWARD ISLAND PHARMACY BOARD

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REGISTRATIONS

Pharmacists: 163
Permits: 40 + 7 hospitals + Provincial Phcy
Students: 25

This newsletter is distributed to all licensed pharmacies in PEI, emailed and posted on our website. Decisions regarding all matters such as regulations, drug related

incidents, etc. are published in it. The PEI Pharmacy Board therefore assumes that all pharmacists are aware of these matters

UPDATING HEALTHREGISTRATION.CA

Pharmacists and Pharmacies are again reminded of their responsibility to notify, **within 7 days**, the Board office about any changes to their registration file. This includes mailing address, place of employment, maternity leave, marital/name status, etc. This can easily be done by phone or email for pharmacies. For pharmacists, this is done through the healthregistration.ca website. When completing data on this site make sure **all the fields are filled in**. Some are providing inaccurate and incomplete data – for example graduated from Dalhousie, but not indicating the country “Canada”. Also, indicating a residency program post graduation, but neglecting to state where and what type.

All information requested is important for national and provincial human resource planning, and provides an overview of how pharmacists are practicing in Prince Edward Island.

PRACTICING PRIOR TO LICENSURE

To become a “licensed pharmacist” in Prince Edward Island, candidates must follow specific steps. When transferring from another jurisdiction, a jurisprudence

exam must be completed, a letter of standing from the present licensing body, application completed and applicable fees paid. Until such time as each step is complete, pharmacists may not practice pharmacy. Presently in PEI one can be a pharmacy student (not yet graduated or completed PEBC) or a Pharmacist. Pharmacists coming from other jurisdictions may not “act as a student or pharmacy technician” while awaiting to complete any step of the process. In the health care setting – patients, co-workers and other health care professionals would look upon you as a pharmacist. This is consistent with other Canadian Provinces, particular in Atlantic Canada. In licensing incoming transfers, the Board has been very flexible in expediting the licensing process and sees no reason for all the steps not to be completed in a timely fashion. In making *any* exceptions, we would jeopardize our present licensing process, our “mutual recognition agreement” with other Canadian jurisdictions, and general liability issues.

METHADONE MAINTENANCE

The Board previously distributed “Methadone Maintenance Guidelines” in the treatment of opioid dependency. The document is available on the PEI section of the NAPRA website. These guidelines were developed for a reason – and the Board is “assuming” all pharmacies are distributing methadone according to these recommendations. This includes lock-boxes, **individual (100ml) Tang-titrated doses**, labeled appropriately. Patients must return their empty bottles prior to receiving any new (carries). As well, there should be a “signing off” by patient and pharmacist for doses/carries received.

Please review these guidelines and supporting documents carefully and be prepared to provide proof of compliance upon any store inspection.

The “Ontario Methadone Maintenance Task Force” has recently released a report from a pilot study regarding delivery of methadone

to the public, whether from community pharmacies or methadone clinics. The Board will be reviewing this intensive document and its findings and recommendations to ensure we are consistent with methadone delivery with across the country.

PRODUCTS WITHOUT A DIN OR NPN *Health Canada reclassification is the reason why*

Pharmacists may have noticed that some non-prescription products, for instance, a popular calcium supplement, no longer carry a DIN on the package or label. There is also no natural product number (NPN).

The reason for this is a move within Health Canada to reclassify non-prescription products that traditionally had a DIN to natural health product status. Manufacturers of affected products must apply for NPNs from Health Canada.

These changes have created a backlog of submissions, hence the lack of a DIN or NPN for products that are in re-application mode. Drug manufacturers can market products without an NPN, as long as Health Canada has an application on file.

Wholesalers can confirm whether an item has an NPN submission number, because they are not allowed to sell unapproved drugs and have a responsibility to ensure a manufacturer has a Health Canada submission number if a product it carries doesn't have a DIN or NPN.

Pharmacists can also contact a manufacturer directly to confirm that an NPN submission has been made to Health Canada and that the manufacturer has received a submission number.

The backlog is expected to be in place for some time: initial bottlenecks were related to natural herbal products; the current slowdown is due to the rescheduling of mineral and vitamin supplements.

RX REFILLS AND BALANCE OWING *Counseling opportunities await*

An ongoing prescription drug regimen can be an indication of a patient's chronic condition. Pharmacists should use refills as a counseling opportunity – don't assume a patient understands his or her condition just because they regularly use a particular prescription drug. For instance, use refills to ask about OTC use or lifestyle changes. Seasonal factors can also be a discussion point, for instance, warfarin patients and a possible increase in green vegetable consumption during summer months.

Similarly, use a balance – owing situation as another counseling opportunity. First, take into consideration patient – privacy issues: ask a patient if it is okay to call them when the balance of their prescription is ready for pick up. Leaving a message with someone at the patient's home about a prescription may inadvertently pass along information that the patient wished to keep private. If the patient doesn't return within a reasonable number of days, this could become a compliance issue, and the prescriber may need to be consulted and the total medication dispensed adjusted.

DIABETES ROUNDUP *Studies underscore counseling importance*

If nothing else, two recent studies show pharmacists have an opportunity to step up to the plate and help patients with diabetes understand their disease and the pros and cons of available treatment options.

Selenium: Maybe not so good

Selenium has a reputation as an antioxidant that maintains glucose metabolism and offers protection against the development of full-blown diabetes. But Rogers Media's PharmacyGateway.ca recently ran an article on a study that found regular selenium supplement use could actually increase the risk of developing diabetes.

Results of the study, which was led by Dr. Saverio Stranges, were published online in the *Annals of Internal Medicine*.

It was a placebo-controlled clinical trial involving 1,200 U.S. patients who did not have diabetes at baseline. The study ran for almost eight years. Fifty-eight patients assigned to the selenium group developed Type 2 diabetes, compared to 39 patients in the placebo group. The article notes, "Patients with baseline plasma selenium levels that were higher than the baseline median value were more likely to develop Type 2 diabetes. The investigators conclude that long-term selenium supplementation does not help prevent the development of Type 2 diabetes and may increase the risk for diabetes. Furthermore, the risk of developing diabetes appears to be higher in patients who have higher baseline selenium levels."

Older, cheaper, better?

"New and improved" may not be so important, after all. A study of diabetes medications recently published in the *Annals of Internal Medicine* and reported on CTV.ca says older and cheaper drugs treat diabetes just as effectively as newer drugs of those with revised formulas. The investigators examined 216 published studies and two systematic reviews of 10 diabetes drugs.

Their findings earmarked metformin (Glucophage®, Glumetza® and generic versions) as one of the most effective diabetes treatments available, and one of the most affordable. It worked well on a number of fronts, controlling blood sugar levels without sending them too low, and did not cause weight gain; in fact, it also reduced LDL cholesterol levels.

CTV.ca reports the study found all of the diabetes meds reviewed had side effects patients should be aware of.

For instance:

- Metformin was associated with greater gastrointestinal problems, along with increased lactic acidosis.
- Repaglinide (GlucoNorm®) was linked to higher incidents of hypoglycemia.
- Sulfonylureas were indicated with an increased likelihood of hypoglycemia. Three drugs in this class are sold in Canada: glyburide (Diabeta®), Euglucon®, and generic versions); gliclazide (Diamicon®, Diamicon® MR, and generic versions); and glimepiride (Amaryl®).

PHARMACY ELSEWHERE

Spain

PharmacyGateway.ca carried the following summer-related tidbit: a Spanish pharmacy in the seaside resort of Fuengirola petitioned the government for an exemption from closing for customary late-afternoon siestas. The pharmacy also applied for an extension of its business hours into the evening, to take advantage of tourist-generated trade. Farmicia La Concha received permission to conduct business from 9:30 a.m. to 10 p.m. daily, because its busiest summer hours are after sunset.

United States

The FDA is looking into developing Schedule II and Schedule III type drug classifications for America's pharmacies. Right now, only a handful of non-prescription drugs are kept in U.S. dispensaries, with most other non-Rx products available for customers to self-select. Keeping many non-prescription drugs behind the counter is common in Canada, Australia, and other nations, but some American stakeholders, particularly physicians, are skeptical. Many U.S. pharmacists see revised drug classification as a new counseling opportunity.

FEDS CHANGE NARCOTIC PRESCRIBING

More health professions enabled under proposal

Health Canada is considering expanding narcotic drug prescribing rights to podiatrists, midwives and nurse practitioners.

Increasing the number of health care professional who can write prescriptions for controlled substances such as oxycodone, morphine, and other potentially addictive drugs is seen by the federal government as one way to take the pressure off of overloaded general practitioners, and streamline prescription needs for many routine procedures. For instance, foot doctors currently have to send a patient to a GP to get analgesics prior to surgery.

But the nature of these powerful medications has some worried that increasing their accessibility could lead to more substance abuse. On July 12, 2007 the *National Post* reported, "It probably makes sense to give the three groups such prescribing authority, said Dr. Benedikt Fischer of the Center for Addictions Research of B.C. However, with Canada using five times as many opiates per capita as the U.K., we need tighter limits generally on the distribution of narcotics, he said."

The Change isn't expected any time soon. Federal laws will first need to be changed, and then the provinces, will need to revise provincial regulations to enable the expanded prescribing rights.

CODEINE SYRUP – dangerous 'near miss' in the community

Problem

ISMP (Institute for Safe Medication Practices) Canada received a medication error report about an error with codeine oral syrup. A seven-year-old boy was seen at an urgent care clinic on a weekend for

symptoms of an ear infection. The attending physician wrote two prescriptions: one for amoxicillin liquid 250 mg po q8h for seven days; and one for codeine syrup 15 mg po q4h prn. The quantity ordered for the codeine syrup was interpreted to be 600 mL. The pharmacist attempted to contact the physician to clarify the volume ordered but was unsuccessful. The pharmacist explained to the patient's mother that the pharmacy had only 500 mL codeine syrup in stock and therefore could not dispense the total volume ordered. He also advised her that he had tried to contact the physician. The pharmacist also recommended that the mother consider giving only half the prescribed dose instead of the full 15 mg dose.

Codeine syrup is available as a 5 mg/mL solution. The recommended dose in children is 1 to 3 mg/kg daily, divided in six doses. The boy weighed 25 kg.

After leaving the store, the mother noticed that the directions on the two 250 mL bottles of codeine syrup were labeled "give 1 tablespoon every 4 hours if needed." From the information provided on the label, she was able to calculate the tablespoon would equate to a 75 mg dose, significantly more than the prescribed 15 mg dose.

Fortunately, she returned to the store and asked the pharmacist to double-check the prescription again, it was realized that the directions on the dispensed product should have read 3 mL per dose instead of one tablespoonful. It was then also surmised that the physician had intended a total quantity of 600 mg and not 600 mL. The label was re-typed and 120 mL of codeine syrup was dispensed.

Contributing factors to the error included workload issues and the lack of an independent check in the dispensing process. The inability to access the prescribing physician in order to verify a prescription is a frustration often experienced in the retail setting.

Safe Practice Recommendations

1. During the prescribing phase there needs to be a risk/benefit analysis of the medication being prescribed. Alternative options (in this case, acetaminophen) should be outlined to the patient and/or family and the decision can then involve the patient and/or their family.
2. Ideally, both the patient/family and the pharmacist should be able to clearly read the prescription. Full information such as the indication and dose calculation, when included in the prescription will also help the checking process.
3. Typically, pharmacies have well - established, redundant systems in place to monitor the accuracy of the dispensing process. A fail-safe process that ensures an independent double check before dispensing medications is critical. As well, the original order should be compared to the final product being dispensed, rather than relying only on the label generated from order entry. "Alarm bells" should be ringing when more than one bottle of a medication is needed to fill a prescription.
4. Unsafe work conditions such as long hours without breaks, multitasking between phones, patients and prescription dispensing, and other workload issues need to be addressed.
5. Ideally, a pharmacy computer system provides a warning when dosed exceed the recommended dose limits.
6. Oral syringes, with instructions on their use, should be provided when pediatric liquids are dispensed. Directions that call for the use of 'teaspoon' of 'tablespoon' increase the risk for harm from error in this patient population.
7. Child-resistant packaging is essential with high-risk drugs such as codeine.

Finally, enhancing patient safety will often require being open to tradeoffs such as ensuring adequate staffing at a higher cost to operations.

DRUG UPDATES

For full details please check:

www.napra.ca

- CADD® Medication Cassette Reservoirs.
- Fluotic® (sodium fluoride) 20 mg tablets.
- Permax® (pergolide mesylate).
- Prexige® (lumiracoxib).
- Rituxan® (rituximab).
- Sensipar® (cinacalcet hydrochloride).
- Xylocaine® (lidocaine HCl) Jelly 2% Single Use Plastic Syringe (10 mL).

AMENDMENT TO THE TPP PRAMOXINE SCHEDULE CLARIFIED

The route of administration affects the schedule of pramoxine-containing products

<i>Use</i>	<i>Schedule</i>
Ophthalmic or parenteral use	2
Topical use on mucous Membranes* (except lozenges)	3
Topical application to the skin (Includes lozenges)	Unscheduled

*Rectal products such as Anusol intended for application to mucous membranes are in Schedule 3.

AMENDMENT TO TPP MEDICATION LIST

Effective October 1, 2007, the TPP medication list was amended:

- Under Bupreorphine—product brand name Subutex® -removed
- Under Buprenorphine – product brand name Suboxone® -added

Buprenorphine has been on the TPP medication list for some time with the example brand name Subutex®. The manufacturer has decided not to market Subutex in Canada; instead it is marketing Suboxone®. Suboxone® is a combination of buprenorphine and naloxone indicated for

substitution treatment in opioid dependence in adults. The combination product is expected to be available in Canada this fall.

To prescribe buprenorphine in PEI, a physician must:

- Hold a menthadone exemption for dependence as a primary care prescriber, and
- Have completed specific buprenorphine training.

Pharmacists are not authorized to prescribe narcotics or controlled drugs.

UPDATED CANADIAN HEALTH GUIDELINES

New contraception, immunization, obesity, and respiratory resources

Contraception

Continuous and extended use combination contraceptives are covered in new guidelines from the Society of Obstetricians and Gynecologists of Canada. Topics include efficacy of continuous and extended regimens, side effects, and women who may benefit most from these contraception regimens (e.g., those with endometriosis, abnormal bleeding, or menstrual-related discomfort).

Immunization

The updated *Canadian Immunization Guide* (seventh edition) has complete inoculation guidelines on efficacy, dosing, side effects and administration for all vaccines available in Canada. It includes information on vaccinating specific patient groups such as pregnant/breastfeeding women, premature infants, and patients with compromised immune systems.

Obesity

These evidence-based guidelines provide a framework for assessing and preventing obesity in Canadian adults and children.

The guidelines, which were published in the *Canadian Medical Association Journal*, include information on the role prescription medications such as sibutramine and orlistat can play as part of a weight-loss regimen for chronically obese adults.

Respiratory

Respiratory (Asthma/COPD) Guidelines for Family Practice is now in its second edition. This publication from the Canadian Respiratory Review Panel is peer-reviewed and evidence-based. The guidelines cover the diagnosis, prevention, and management of asthma and chronic obstructive pulmonary disease (COPD). Pharmacotherapy portions include treatment/disease severity tables and daily dosage and daily cost information.

Continuous/extended contraception – www.sogc.org/media/pdf/cont-ext-contraception_guideline_e.pdf

Immunization – www.cmaj.ca/cgi/content/full/176/8/S1/DC1

Obesity – www.phac-aspc.gc.ca/pulicat/cog-gci/index.html

Respiratory – www.mushealth.com

DEATH IN CANADA TIED TO COUNTERFEIT DRUGS BOUGHT VIA INTERNET

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

COUNTERFEIT PHARMACEUTICALS

Since 1999, NABP (National Association of Boards of Pharmacy) in the United States Verified Internet Pharmacy Practice Sites™ program has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

UNCLEAR MEANING OF PRESCRIPTION

Courtesy of: Pharmacy Connection, September/October 2007

Pharmacists often encounter physician handwriting that is difficult to decipher. Misinterpretation of the poor handwriting is a common cause of medication error. In some cases, the prescriber's handwriting is clear. However, the intended meaning can be ambiguous or unclear. The following case highlights this issue.

CASE

Oxycodone 10mg PO BID x 90 days

The daughter of an eighty year old patient took the above prescription to her regular pharmacy for processing. The pharmacy technician entered the prescription into the computer as 180 Oxy-IR® 10 mg (oxcodone HCl immediate release) tablets to be taken twice daily. The technician then prepared and labeled the tablets for checking by the pharmacist. The pharmacist checked the prescription, contents of the vial, and after signing the prescription, placed the medication in the drawer for pick up.

The following day, the patients' daughter returned to the pharmacy to pick up the medication. On this occasion a second pharmacist retrieved the medication to counsel the daughter on how the tablets should be taken. Upon reading the labeled instructions for use as twice daily for the

immediate release tablets, the pharmacist decided to check the original prescription to confirm that the information had been entered into the computer correctly. On checking the directions for the prescription prior to counseling the daughter, the second pharmacist was uncomfortable with the twice daily instructions used with an immediate release tablet. He then explained to the patient's daughter that he will need to contact the prescriber to confirm his intention. Upon contacting the prescriber, he confirmed that he had intended to prescribe oxycodone controlled release tablets (Oxycontin® 10 mg) to be taken every twelve hours

Possible Contributing Factors

1. The prescriber did not specify the formulation to be dispensed.
2. Most of the prescription was written by a support staff at the doctor's office. The prescriber added the days supply to be dispensed and signed the prescription.
3. Initially, the dispensing pharmacist did not contact the prescriber to clarify the ambiguous prescription.
4. The dispensing pharmacist did not identify the twice daily dosing as inappropriate for the immediate release tablets.
5. The dispensing pharmacies did not check the patient's medication history to notice that the patient was currently taking Oxycocet® every four hours when necessary.
6. Both Oxy-IR® and OxyContin® are available in a 10 mg strength tablet.

Recommendations

- Check the instructions for use for appropriateness.
- Use the patient's medication history to assist in confirming the appropriateness of the drug prescribed.
- Always contact the prescriber to clarify prescriptions that are ambiguous.

- Use the opportunity to counsel as the final check on the appropriateness of the medication.

PRACTICE RESOURCES

CADTH

The Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies.

In addition to numerous tools and reports available on their website, they also offer informative supplements. Newsletters and reports covering emerging drugs, health technologies, and up-to-the minute techniques are available by free subscription. Check out this great resource at www.cadth.ca/index.php/en/home.

PANDEMIC PLANNING

The Canadian Pharmacists Association has a wealth of resources on pandemic planning available on their website. You can find pandemic resources in the Practice Resources section of their website at www.pharmacists.ca.

CORONER'S RECOMMENDATION: FONT SIZE

Minimizing Patient Risks in Methadone Administration: Labeling

A coroner's inquest was held in Nov. 2006 to consider the death of a patient by oral overdose of prescribed methadone. One of the recommendations of the jury was:

Ontario pharmacies should increase the font size of the patient name and dosage amount on the labels of methadone bottles

In contrast to other narcotics, requirements for the prescribing, dispensing and

administration of methadone can be challenging.

To minimize the risk of providing the wrong dose or administering to the wrong patient, pharmacists should review their labeling practices for methadone drinks. In addition to the requirements for labeling, methadone drinks are compounded products which adds to the complexity of the information on the label. This can be confusing for both the pharmacist and the patient.

The Standards of Practice expect pharmacists to resolve different labeling challenges as they arise, such as labeling for small containers like ophthalmic preparations, visually challenged individuals, language problems and methadone.

To address patient safety, patient needs, different models of administration and increasing numbers of patients on methadone, pharmacists should review labeling. Some areas to consider are to:

- Highlight the name of the patient and dose with use of a highlighter
- Increase and/or bold the font to stand out from the rest of the information
- Ensure the direction is clear
- Eliminate non essential information
- Reduce the font on the other required information

Following the Standards of Practice will assist pharmacists in making their decision as to when it should be appropriate to take additional measures when labeling.

QUESTION & ANSWER

A patient asked me if we have started to carry Imodium® Liquid for Adults (it contains loperamide 2 mg per teaspoonful). We will be getting a supply shortly – can this product be sold from the Schedule III area outside the dispensary?

The labeling includes dosing for children as well as adults; because of this it remains a

Schedule II drug, and the product must be sold from a dispensary's professional services area to which there is no public access.

SPECIALTY CERTIFICATION

The Board is working with the Canadian Council on Continuing Education is Pharmacy (CCCEP) and NAPRA for the establishment of a national accreditation process for post-entry to practice certificate programs in Pharmacy. A process will be developed to accredit the various pharmacy "specialty" programs available to practitioners to determine their validity and appropriateness.

Pharmacists are reminded that until such time as specific programs are accredited by CCCEP, pharmacists **cannot** advertise or make any claim to advanced practice/specialty in the context of their license to practice pharmacy.

CONTINUING EDUCATION LOGS

Pharmacists are reminded that Continuing Education Logs are due to be **in** the Board office by January 31, 2007. Copies of the log are available in the PEI section of www.napra.ca

IMPORTANT SAFETY ADVISORIES

Pharmacists, especially pharmacy managers, are reminded that critical health/drug advisories, warnings and drug recalls are posted on the NAPRA website, as well as on the Health Canada website. **It is the responsibility of every licensed pharmacist to keep abreast of these safety advisories and to advise their patients when appropriate.**

Additionally, on the NAPRA website you can report any adverse drug reactions encountered in your practice directly to Health Canada.